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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/803,279 | 03/18/2004 | M. David Butts | 480062004300 | 5654 |
| 25224 | 7590 | 05/31/2007 | EXAMINER | |
| MORRISON & FOERSTER, LLP | | | BOUCHELLE, LAURA A | |
| 555 WEST FIFTH STREET | | | ART UNIT | PAPER NUMBER |
| SUITE 3500 | | | 3763 | |
| LOS ANGELES, CA 90013-1024 | | | | |

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/803,279 | BUTTS ET AL. |
| | Examiner | Art Unit |
| | Laura A. Bouchelle | 3763 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 01 March 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.
 - 4a) Of the above claim(s) 4 and 26-45 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 and 5-25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/1/07
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 6, 9, 10, 12, 13, 17, 18, 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellotti et al (US 4596571). Bellotti discloses a shroud for a connection site comprising a body 40 having a cannula 12 and a tail 22. Both the cannula and the tail are configured to receive a tube or a catheter thereon. The first 26 and second 28 portions of the mating connector are connected by a hinge 30. The cannula extends from a head 44.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 2, 3, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellotti in view of Clark et al (US 4723948). Claim 2 differs from Bellotti in calling for the body and the securement device to be unitary. Clark teaches a catheter attachment system wherein the body and the securement device are unitary which minimizes local stresses on the catheter in the region of the connection (Col. 2, lines 41-44). Therefore, it would have been obvious to one of

ordinary skill in the art at the time of the invention to modify the device of Bellotti so that the body and the securement device are unitary as taught by Clark to minimize local stresses on the catheter in the region of the connection.

5. Claim 7 differs from Bellotti in calling for the tail to have a barbed end. Clark teaches the use of a barbed end on the end of the cannula being inserted to function as a guide to center the cannula in the lumen and to engage the inner surface of the lumen (Col. 3, lines 15-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the end of the tail barbed as taught by Clark to guide the tail into the tube and to engage the inner wall of the tube.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bellotti in view of Fonger et al (US 5190528). Claim 8 differs from Bellotti in calling for the open end of the cannula to be rounded. Fonger teaches a cannula with a rounded distal end to prevent scraping within the catheter when the cannula is inserted into the catheter (Col. 3, lines 44-46). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cannula of Bellotti to have a rounded open end as taught by Fonger so that the cannula will not scrape within the catheter when it is inserted.

7. Claims 14- 16, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellotti in view of Wilson et al (WO 02/058776) in further view of Brimhall et al (US

2003/0065288). Claims 14 and 21-25 differ from Bellotti in calling for the connector to comprise a winged covering apparatus. Wilson teaches a catheter having a connection cover 34 that prevents inadvertent separation of the catheter tube from the connector after insertion of the catheter into the patient (Page 8, lines 6-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bellotti to include a cover as taught by Wilson to prevent inadvertent separation of the catheter tube from the connector after insertion of the catheter.

8. Claim 14 further differs from the teachings of Bellotti in view of Wilson in calling for the covering to comprise wings. Claim 15 further calls for the winged covering apparatus to be made of silicone. Brimhall teaches the use of wings to facilitate taping or suturing of the catheter to the patient's skin (Page 1, Paragraph 0004). Further to maximize patient comfort, Brimhall teaches that the wings be made of a soft, flexible material such as silicone (Page 1, Paragraph 0005). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the covering of Bellotti in view of Wilson to have silicone wings as taught by Brimhall to facilitate taping or suturing of the catheter to the patient's skin and to maximize patient comfort.

9. Claim 16 differs from Bellotti in calling for the body to have a non-uniform outer surface, and the winged portion to have a non-uniform inner surface. Wilson teaches that the cover fits axially about the catheter tube and it attachable by a non-uniform inner surface that meshes with a non-uniform outer surface of the catheter to securely attach the cover to the body (Page 7,

Lines 18-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Bellotti to include a cover with a non-uniform inner surface that meshes with the non-uniform outer surface of the body as taught by Wilson to securely attach the cover to the body.

10. Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bellotti view of Bellotti (EPO 0183396 A1) [Hereinafter Bellotti II]. Claim 11 differs from Bellotti in calling for the catheter receiving portion of the mating portion to funnel outward. Bellotti II teaches that the bore of the connector is funneled outward so that the bore does not engage the inserted cannula until it is advanced further into the connector (Page 3, lines 13-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the connector of Bellotti to have a funneled end as taught by Bellotti II so that the cannula is not immediately engaged with the connector upon insertion.

11. Claim 20 differs from Bellotti in calling for the mating portion to include catheter gripping liners. Bellotti II teaches a connector having a catheter gripping liner 48 that surround and protect the catheter when the mating portions are closed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the connector of Bellotti to have catheter gripping liners as taught by Bellotti II to surround and protect the catheter.

Response to Arguments

12. Applicant's arguments filed 3/1/07 have been fully considered but they are not persuasive.
13. Applicant argues that Bellotti does not teach a catheter connector body having a tail configured to receive a tube thereon. The examiner believes that the portion of the device signified by reference numeral 22 of Bellotti is capable of receiving a tube thereon.
14. Applicant argues that the combination of Fonger with Bellotti would render Bellotti unsatisfactory for its intended use. However, the device of Bellotti does not say that a tapered point is required to puncture the septum. Bellotti is silent on the makeup of the septum, and it is conceivable that the septum need only a rigid member to puncture it. Furthermore, as taught by Fonger, a rounded end would prevent puncture of fluid container to which the connector is being attached.
15. Applicant argues that there is no motivation to combine Bellotti with a cover having wings because Bellotti is used with a CAPD device. The examiner believes that it is obvious to combine these teachings as Bellotti discloses "devices intended to surround and protect the connection site between fluid conduits, particularly in the medical field" (Col. 1, lines 7-9) and although Bellotti uses a CAPD device as an example, the device can be used "in a diverse number of environments" (Col. 2, line49) or "in the administration of parenteral fluids in general" (col. 2, lines 54-55).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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